APR 2 0 2001

K010846
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510(k) Summary
Special 510(k): Device Modification
SynPlug™

1. SPONSOR

IsoTis NV
Prof. Bronkhorstlaan 10-D
3723 MB Bilthoven
The Netherlands

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Telephone: +31 (0) 30 2295125

Date Prepared: March 20, 2001

2. DEVICE NAME

Proprietary Name: SynPlug™
Common/Usual Name: Cement restrictor
Classification Name: Cement obturator

3. PREDICATE DEVICE

Shuttle Stop® (K000587)

4. DEVICE DESCRIPTION

The proposed SynPlug™ cement restrictor is identical in intended use and fundamental scientific technology to the parent Shuttle Stop® cement restrictor that was cleared for marketing by FDA on May 4, 2000 (K000587). Design changes were made to prevent cement leakage and migration, increase pressure resistance, and improve the ease of handling of the cement restrictor. These design modifications are limited to the following:

- Adoption of a cylindrical shape for the proposed SynPlug
- Elimination of sidewall slots and addition of five flanges

- Increase in the rigidity of the proposed device
- Expansion of the number of available sizes for the proposed device to 13, designed to fit intramedullary canal diameters of 9 to 21 mm

This submission also contains a description of instrumentation sets that have been developed to facilitate the selection of cement restrictor size by assessment of the intramedullary canal diameter and provide correct insertion of the cement restrictor. The SynPlug Instrumentation Set consists of 14 measuring probes for the measurement of canal diameters from 9 to 21 mm, two insertion rods, and a sterilization tray for holding the instruments during sterilization. The Shuttle Stop Instrumentation Set is identical to the SynPlug Instrumentation Set with the exception that only five measuring probes are provided to correspond with the four sizes of Shuttle Stop and a probe measuring the maximum intramedullary canal diameter for which the largest size Shuttle Stop can be used, 8 to 20 mm.

5. INTENDED USE

The SynPlug is a cylindrical plug intended for intramedullary occlusion during cemented hip and shoulder arthroplasty.

6. BASIS OF DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The proposed SynPlug is a modification of the Shuttle Stop and is therefore substantially equivalent to the Shuttle Stop cement restrictor. The intended use and technological characteristics of the proposed and parent devices are identical. Differences are limited to the design modifications listed in Section 4. These design modifications were validated according to IsoTis' Design Control Procedures, in compliance with the design control procedure requirements of the Quality Systems Regulations as specified in 21 CFR 820.30. The differences between the proposed and parent devices are minor and do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2001

IsoTis NV
c/o Cynthia J. M. Nolte, Ph.D.
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K010840
Trade Name: SynPlug™
Regulation Number: Unclassified
Product Code: LZN
Dated: March 20, 2001
Received: March 21, 2001

Dear Dr. Nolte:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010840

Device Name: SynPlug™

Indications for Use:

SynPlug™ is a cylindrical plug intended for intramedullary occlusion during cemented hip and shoulder arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010840

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)